



MEMORANDUM #26

TO: UNCHCS Attending Physicians, Housestaff, Clinical Nurse Coordinators, Department Heads and Supervisors

FROM: *NM* Nathan Montgomery, MD, PhD, Director, Molecular Hematopathology
KW Karen Weck MD, Director, Molecular Genetics Laboratory
HCU Herbert C. Whinna MD, PhD, Medical Director, McLendon Clinical Laboratories

SUBJECT: **Replacement of the Lymphoid Mutation Panel at UNC with *TP53* and *BRAF* Single Gene Sequencing Assays**

DATE: March 25, 2019

Effective March 31, 2019, the UNC Lymphoid Mutation Panel will be discontinued and replaced by two new single gene sequencing assays: ***TP53* somatic mutation testing – hematologic malignancies** and ***BRAF* somatic mutation testing – hematologic malignancies**.

Clinical indications for testing:

1. ***TP53* somatic mutation testing – hematologic malignancies:** *TP53* mutation status is prognostically informative and may guide therapy decisions in chronic lymphocytic leukemia (CLL) and some other lymphoid malignancies, such as mantle cell lymphoma.
2. ***BRAF* somatic mutation testing – hematologic malignancies:** *BRAF* mutation is found in nearly all cases of hairy cell leukemia (HCL) but typically not in other splenic leukemias/lymphomas.

Why is this change occurring?

1. Individual gene testing is better aligned with the current standard-of-care/National Comprehensive Cancer Network guidelines.
2. Because lymphoid mutation panel testing continues to be classified as “experimental” by some major insurers, transition to single gene testing will decrease the risk of significant out-of-pocket expenses to UNC patients.

Options for continued panel testing in patients with lymphoid malignancies:

All genes in the discontinued UNC Lymphoid Mutation Panel will continue to be offered as part of the **UNC Myeloid Mutation Panel**, which can be ordered on peripheral blood or bone marrow (see McLendon labs website, below)

Specimen Requirements: Bone marrow aspirate (1mL EDTA) or peripheral blood (3mL, EDTA) having at least 10% neoplastic cells and refrigerated for up to 72 hours before analysis. Variants are reported to a limit of detection of 5.0% variant allele fraction.

Questions: Email Nathan Montgomery (Nathan.montgomery@unchealth.unc.edu), or call the UNC Molecular Genetics Lab at (984) 974-1825.

Website: <https://www.uncmedicalcenter.org/mclendon-clinical-laboratories/directory/molecular-pathology-and-genetics/>.